89. The 2002 Marketing Strategy Presentation reflected Organon's scheme to entice pharmacists to convert prescriptions from Remeron Tablet to Remeron SolTab by marketing the spread and offering illegal, financial incentives to increase that spread.

c. The "Remeron SolTab Therapeutic Interchange Toolkit"

90. It was after Remeron SolTab was launched in January 2001 that Organon's Marketing Department hired pharmacist Dana Saffel to speak as a paid consultant covering both clinical and financial topics. As a part of her employment, Saffel also designed formal marketing materials to market the new product's "spread" and other financial incentives to pharmacy providers. The notebook that she helped to create, "Remeron SolTab Therapeutic Interchange Toolkit" ("Toolkit") and its accompanying CD and "Profit Calculator," makes visible and undeniable Organon's marketing practices. It is the "smoking gun" that demonstrates beyond any doubt that Organon specifically marketed to pharmacies the opportunity to profit illegally from Remeron prescriptions at Medicaid's expense. In 2006, when the advent of prescription eligibility under Medicare Part D finally rendered such marketing obsolete, Organon management was eager to bury such evidence of its longtime marketing practices in long-term care. Relators nevertheless obtained a copy of the notebook, attached as Exhibit 1.

Organon's Toolkit Was Distributed to LTC Customers to Sell the Opportunity to Profit by Increasing Remeron SolTab Scripts

91. These printed materials were widely used by the Organon Long Term Care sales force as the primary tool for selling to both long-term care clinicians and long-term care pharmacy consultants. Dana Saffel's cover letter to the notebook made plain that the Toolkit was designed, not to be used by Organon salespeople, but to be used by long-term care pharmacy providers themselves. The cover letter named two purposes for the notebook: to persuade the

pharmacy provider why it should choose Remeron SolTab as its "preferred anti-depressant agent for a large percentage of your frail elderly patients," and to teach the pharmacy provider how to "implement a therapeutic interchange program" that would successfully promote the preferred drug to patients' prescribers. Toolkit, Exhibit 1, Cover Letter, p. 1.

Organon's Toolkit Promoted Remeron's Sedative Qualities and Convenience for LTC Administrators in the Name of "Therapeutic Efficacy"

92. Section I of the Toolkit was devoted to Remeron's "therapeutic efficacy," but in addition to the drug's pharmacological properties, the section discussed costs to Medicaid and convenience in administering and storing the drug. Indeed, even the portions of this section devoted to the drug's pharmacological properties discussed Remeron's supposed economic benefits to pharmacy providers and nursing homes. On page 2 of Section I, for example, Remeron's chief side effects, including "somnolence," were proclaimed both "beneficial" and "attractive." *See* Toolkit, Exhibit 1. On page 41, the Toolkit suggested that the "most appropriate" anti-depressant for nursing home resident is one that, among other qualities, "improve[s] reimbursement under PPS" for the resident's care by elevating the patient's reimbursement level and "reduce[s] staff time required for care."

Most Importantly, Organon's Toolkit Advised LTC Customers to Adopt Remeron as Their Preferred Anti-Depressant Based First and Foremost on Their Opportunity to Profit at Medicaid's Expense

93. Section II of the Toolkit spelled out the bottom line for pharmacy providers: the opportunity to increase profits by encouraging the prescribing of Remeron. This section, entitled "Contract Evaluation," explicitly described Medicaid's reimbursement formulas based on AWP and WAC, then devoted a page to defining "spread" as the difference between Medicaid's reimbursement amount and the pharmacist's acquisition costs, taking into account any discounts

provided for by contract. On this subject the Toolkit advised that while "[e]thical decisions must be made as to the total cost of the drug to [Medicaid],"

> Whenever possible, products should be chosen that provide the highest spread for the pharmacy and the lowest cost to the payor [Medicaid], keeping in mind that this choice of product should also provide the greatest therapeutic benefit with the least risk to the patient.

Toolkit, Exhibit 1, Section II, p. 3 (Emphasis in original). Remarkably, the Toolkit actually touts a low AWP cost to Medicaid as a more important reason to prefer a drug than therapeutic benefit, though less important than personal profit. Organon apparently adopted this arguably altruistic factor out of necessity: Remeron's spread was large, but not the largest in its class, while its AWP was relatively low compared with other anti-depressants. But Organon's willingness to promote Remeron's low AWP while simultaneously offering pharmacy providers profits at Medicaid's expense demonstrates just how desperate Organon was to hold onto Remeron revenue. Medicaid, presumably, would have preferred that Organon simply report its pricing honestly to begin with, and that LTC pharmacies allow *physicians* to guide drug choice for patients on an individual basis with therapeutic benefit in mind.

94. Again on page 17, the Toolkit similarly listed profit to the pharmacy as the most important factor and actual benefit to the patient as the least important factor to consider. *See* Toolkit, Exhibit 1. The page was (perhaps ironically) entitled, "Ethics and Morality," and it counseled:

> Pure profit alone can never be the sole deciding factor on which drug should be preferred. Contracting evaluations should always favor the drug that offers:
>
> - the highest spread for the pharmacy
> - the lowest AWP cost to the payor
> - the highest benefit to risk for the patient.
>

Toolkit, Exhibit 1, p. 17.

95. The remainder of Section II was devoted to assisting the pharmacy provider in assesing the most important factor: its own "opportunity to profit" from promoting Remeron scripts. Pages 4 and 5, entitled "$pread Comparison$," compared different anti-depressants' spreads, excluding discounts, and highlighted Remeron's and two other drugs' spreads as "favorable." The Toolkit defined "opportunity to profit" as the "extra" profit a pharmacy realizes when a preferred drug with a bigger spread is prescribed instead of another drug in the same therapeutic class. *See* Toolkit, Exhibit 1. It then went on to describe various discounts and rebates available during that time, including an initial 2% discount off Remeron's WAC price, a limited-time 14% ramp-up rebate, and a range of rebates based on market share to be available after the ramp-up. Toolkit, Exhibit 1, Section II, p. 6. The Toolkit advised that given those rebates and discounts, Remeron SolTab carried a maximum spread of $.82 per tab. In choosing a preferred anti-depressant, customers were urged to consider also cost savings stemming from Remeron Tablet and Remeron SolTab's supposed ability to treat anxiety as well as depression, possibly eliminating the need for a second prescription. In addition, the Toolkit suggested that the customer consider Remeron SolTab's low AWP cost to Medicaid in determining that the drug represented the best opportunity for revenue. Toolkit, Exhibit 1, Section II, p. 6.

96. In the guise of allaying fears that a pharmacy will lose money if it substitutes Remeron SolTab for an anti-depressant that is prescribed in combination with an anti-anxiety drug, the Toolkit seized the opportunity to warn that Medicaid reimburses for generic drugs at very low prices, sometimes less than the administrative costs of disbursing and administering them. Toolkit, Exhibit 1, Section II, pp. 15-16. A customer is therefore better off disbursing a name-brand, single-source drug like Remeron SolTab than a generic anti-depressant.

97. If, however, the customer receives similar discounts and rebates under contracts with other anti-depressants, calculating which drug provides the greatest profits requires a little more work, the Toolkit pointed out. Toolkit, Exhibit 1, Section II, p. 7. It therefore provided a convenient worksheet for comparing AWP, acquisition costs, spread, rebates, gross profits, and opportunity to profit for each drug in Remeron's therapeutic class, with the AWP already filled in. Toolkit, Exhibit 1, Section II, p. 11-13. In addition, the manual was accompanied by a branded electronic diskette titled with the same name ("Toolkit CD") that housed a financial model meant to encourage long-term care customers to calculate even more easily their relative spread and profit.

Organon's Toolkit Showed LTC Customers Exactly How to Control Which Anti-Depressant Was Prescribed to Their Disabled and Elderly Patients

98. A major purpose of hiring Saffel was to develop a set of materials for pharmacy providers to use to convert prescriptions to Remeron SolTab from both Remeron Tablet and other anti-depressants. Section II of the Toolkit includes step-by-step directions for "implementing a therapeutic interchange" using both the Remeron drug information in Section I, in addition to a full portfolio of materials she developed for that purpose. These materials were also included on the accompanying CD as templates.

99. The Toolkit CD advised that a pharmacy could reach the maximum market share attainable for a preferred drug in three to six months. It laid out a timeline that began with planning and moved on to physician notification, "point-of-disbursing intervention," and monitoring. As the Toolkit CD pointed out, converting prescriptions is simple under a "collaborative practice agreement," in which a physician broadly authorizes a pharmacist to initiate, change, discontinue, and/or monitor patient medications. Some long-term care facilities

incorporate such an agreement into their policies and procedures. Where this exists in its broadest form, the only communication to a physician is a notification of the change.

100. As an alternative, the Toolkit CD suggested a subtler method for obtaining physician authorization. In a typical long-term care facility, a physician signs orders for his or her patients on a monthly basis. The Toolkit recommended including a broad "authorization phrase" on this Physician's Order Summary such as:

> "May use alternate dosage form of ordered drug if necessary and appropriate" (would allow conversion from Remeron Tablet to Remeron SolTab);
> or
> "May perform therapeutic interchange on appropriate drugs per facility policy" (even broader)

That way, the Toolkit CD suggested that "[o]nce the physician has signed the monthly orders, he has authorized the activity."

101. The Toolkit CD included these template "tools" for increasing Remeron SolTab's market share:

- **Introductory letter to physicians:** Extols virtues of Remeron, with attached chart of applicable patients and authorization and clinical studies.
- **Memorandum to facility administrators announcing Remeron SolTab as preferred drug:** Focusing on efficiency, convenience, regulatory issues, states that pharmacy "will be identifying those residents who may benefit from Remeron SolTab as we visit your facility and will be making appropriate recommendations to the attending physician."
- **Announcement to Facility Staff:** States that "[a]ll Remeron orders will be converted to this new and easy to administer dosage form."
- **Several example prescriptions to insert in consulting pharmacists' patient-specific recommendations:** To move resident to Remeron SolTab from Remeron Tablet or other anti-depressants. For different indications, including swallowing problem, anxiety, weight loss, insomnia, "administrator's slant" and "director of nursing slant." The Toolkit CD suggested adding boxes for yes or no for the physician to check.

- **Point-of-disbursing intervention forms:** "Clinical alerts" to send to physicians when a refill order is received or when a physician defies earlier requests and writes a new prescription for a non-preferred drug, asking for permission to convert the prescription to Remeron SolTab. The Toolkit CD also recommended at this point calling facility staff to win their support, then calling the physician.

102. In Section II, the Toolkit actually hypothesized that, if five pharmacists each spent one overtime day calling 11 physicians an hour, spending five minutes on each call, they could convert 444 prescriptions at labor costs of only $2,500 and still save over $56,000 every month by converting to Remeron SolTab.

103. The Toolkit makes abundantly clear just how much influence pharmacists have over what product is prescribed to long-term care residents of their facilities, and just how much profit is at stake when they wield that influence.

F. Discounts and Rebates Offered to GPOs and Long-Term Care Pharmacy Providers

104. As time went by, Organon began to offer discounts and rebates on Remeron only to long-term care members of these GPOs. Then, after Remeron SolTab's launch, Organon removed discounts and rebates on Remeron Tablet and offered extra incentives to convert scripts from the old to the new Remeron product, including a "conversion rebate" and a "therapeutic interchange rebate." In addition, Organon increasingly moved away from price discounts, which benefit the purchaser at the time of purchase, and toward off-invoice rebates, which are paid back to the purchaser later. A February 1, 2002 internal Organon memorandum from John Ocejo to Sam Michini underlines the rationale for these changes, noting that, as of that date, only 15% of MHA's and GeriMed's Remeron scripts had been converted to the SolTab form. Consequently, new GPO contracts for long-term care negotiated with three of the four GPOs included the following:

- Aggressive ramp-ups that applied only to Remeron SolTab;
- All Remeron Tablet incentives were eliminated, including the administrative fee;
- An increased administrative fee on Remeron SolTab;
- Financial incentives changed from predominantly discounts with a small added rebate to mainly rebates with a small discount; and
- Market tier rebates demanded high market share and conversion rates to maintain the same price as during ramp-up.

105. A review of Organon's internal long term care contract files for GPOs, GeriMed, MHA, Committed Provider Services ("CPS"), and Owen, and long-term care pharmacy provider, PharMerica, reveals the following history of illegal financial inducements to encourage Remeron prescriptions.

i. GeriMed

106. GeriMed is a pharmaceutical group purchasing organization ("GPO"). The first contract between Organon and GeriMed for which Relators have pricing exhibits went into effect on February 17, 1999. It provided that in exchange for promoting Remeron to its members, GeriMed would receive an "Administrative Fee" equal to 2% of its members' total Remeron purchases. In addition, Organon offered an **8%"ramp-up" charge-back discount** for the first five months, followed by **8% to 15% chargeback discounts** after that, dependent on Remeron's market share for that member. These market-tier discounts were based on the performance of individual long-term care pharmacy providers, not the performance of the GPO as a whole. A May 1, 1999 Amendment to that agreement increased the ramp-up chargeback amount to an enormous **14.8%**, the largest ramp-up Organon ever offered to the GPO.

107. After Remeron SolTab was launched, Organon focused on promoting the new Remeron product to long-term care facilities by offering new and exclusive incentives to GeriMed's long-term care members only. The parties' March 1, 2001 contract (signed two months after Remeron SolTab' launch), included a **12% limited-time ramp-up chargeback**

Lead BK: 95-48474 96-04098 Kukui Inc et al v. McKenzie et al **CASE CLOSED on 04/20/1999** *Office:* 4	308	*Entered:* 11/09/2007 08:35:24 *Filed:* 11/08/2007	*Category:*court *Event:* Abstract Issued	*Judge:* Greendyke *Trustee:* Smith	*Subm. by:* jdav *Chapter:* *Type:* ap *Group:* crt
Lead BK: 07-35276 07-03475 Arceneaux v. US Department of Education et al *Office:* 4	4	*Entered:* 11/09/2007 11:52:40 *Filed:* 11/09/2007	*Category:*court *Event:* Summons Issued	*Judge:* Brown	*Subm. by:* jdav *Chapter:* *Type:* ap *Group:* crt
	5	*Entered:* 11/09/2007 11:55:41 *Filed:* 11/09/2007	*Category:*court *Event:* Summons Issued	*Judge:* Brown	*Subm. by:* jdav *Chapter:* *Type:* ap *Group:* crt
07-37801 Bryan Wesley Butler and Lisa Michelle Butler *Office:* 4	5	*Entered:* 11/09/2007 08:40:48 *Filed:* 11/08/2007	*Category:*court *Event:* Declaration for Electronic Filing and Statement of SSN Submitted	*Judge:* Brown *Trustee:* Williams	*Subm. by:* jdav *Chapter:* 7 *Type:* bk *Group:* crt
07-37821 Luis Arturo Pena and Karina Nunez *Office:* 4	5	*Entered:* 11/09/2007 08:37:13 *Filed:* 11/08/2007	*Category:*court *Event:* Statement of Social Security Number(s) Submitted	*Judge:* Steen *Trustee:* Hill	*Subm. by:* jdav *Chapter:* 7 *Type:* bk *Group:* crt
07-80590 Mark E Reid *Office:* 3	14	*Entered:* 11/09/2007 08:39:12 *Filed:* 11/08/2007	*Category:*court *Event:* Statement of Social Security Number(s) Submitted	*Judge:* Clark *Trustee:* Heitkamp	*Subm. by:* jdav *Chapter:* 13 *Type:* bk *Group:* crt

discount and, after expiration of the ramp-up period, a 5% to 12% chargeback discount after that based on market tier. But it also included a new **"conversion rebate" of up to 3%** for scripts converted from Remeron Tablet to Remeron SolTab, and a **1.5% "therapeutic interchange" bonus** for agreeing to give Remeron Tablet or Remeron SolTab a "preferred product status" and to implement a Therapeutic Interchange Program to get patients prescribed on the new drug. It also added comprehensive new requirements to promote Remeron to GeriMed's members.

108. Those market-tier rebates were included in succeeding contracts through 2004, with 14% ramp-up discounts repeatedly offered.

109. In 2003, GeriMed's administrators copied Organon on a memorandum advising GeriMed's members that, although Teva Pharmaceuticals was about to introduce the first generic facsimile of Remeron SolTab, and the AWP and WAC for Teva's product was higher, suggesting a greater spread, their greatest profit lay in continuing to encourage Remeron SolTab scripts, given Organon's discounts:

> **Currently, the best scenario for your pharmacy is to stay with Remeron SolTab and/or finish converting your Remeron tabs to Remeron SolTab especially with the discounts from Organon.**

(Emphasis in original).

110. Organon finally allowed its Remeron contract with GeriMed to expire on December 31, 2005 because the Medicare Part D prescription was to supersede Medicaid for long-term care residents beginning the following day, and that program was expected to mandate generic equivalents where available.

ii. Managed Healthcare Associates, Inc. ("MHA")

111. MHA is, like GeriMed, a GPO, which, as nicely defined in MHA's Long Term Care Agreement with Organon, is "a cooperative of health facilities . . . that attempts to achieve the best price offerings for products and services for its Members." Its February 17, 1999 contract with Organon pledged **ramp-up discounts of 14.8%** (compared with GeriMed's 8% during the same period). Even in 1999, such discounts were offered only to the GPO's long-term care members.

112. On January 24, 2001, just as Remeron SolTab was launched, MHA and Organon signed a new agreement, which, like GeriMed's during the same period, instituted new promotion requirements, **"conversion rebates"** and **"therapeutic interchange bonuses"** applying only to the new Remeron product. **12% to 14% ramp-up rebates** for Remeron SolTab predominated from 2001 through 2004. These market-tier discounts were derived at the individual long-term care pharmacy provider level and were not based on consolidated performance by all GPO members.

iii. Owen

113. Organon and Owen Healthcare, Inc. ("Owen") entered into an agreement on March 1, 2001 that employed the same basic terms as GeriMed's and MHA's, and included a **12% ramp-up discount through September 30, 2001, followed by 5% to 12% discounts based on market tier in the post ramp-up period, plus a 1.5% therapeutic interchange bonus and a conversion rebate of up to 3%**, all available only to long-term care members. These market-tier discounts were derived at the individual long-term care pharmacy provider level and were not based on consolidated performance by all GPO members. WAC prices increased, but discount and rebate percentages remained the same in a June 2001 amendment.

With a new agreement becoming effective on March 1, 2002, **the ramp-up discount increased to 14%, while the market tier rebates ranged from 4% to 16%.** A **9.5% rebate was offered only on Remeron Tablet until April 30, 2002**, but no conversion rebate was offered. A March 2002 amendment to that agreement reflects that the parties had negotiated the **addition of a conversion rebate** to Exhibit B after Owen began shifting Remeron Tablet prescriptions to Remeron SolTab scripts. **Several amendments through 2003 extended the 14% ramp-up discount**, but reduced the market share tiers downward.

iv. Committed Provider Services

114. In January 2001, after the launch of Remeron SolTab, Organon entered into a chargeback contract with Committed Provider Services. Like GeriMed and MHA, Committed Provider Services is a GPO, whose purpose as defined in the contract is to "achieve the best price offerings for products and services for its Members." The contract between Organon and Committed Provider Services employed the same basic terms as GeriMed's and MHA's, providing for a **12% ramp-up discount through September 30, 2001 and a 5% to 12% chargeback discount** after that based on market tier. The contract also included a **1.5% therapeutic interchange bonus and a conversion rebate of up to 3%** for prescriptions converted from Remeron Tablet to Remeron SolTab available only to long-term care members of Committed Provider Services. Organon terminated the contract on April 20, 2002.

v. PharMerica

115. After Organon's termination of its contract with Committed Provider Services, Organon entered into a contract continuing the rebate agreements with one of the long-term term care members of Committed Provider Services—PharMerica. PharMerica is also Organon's largest customer. While Relators have not located that contract and cannot determine the

original ramp-up discount percentage, a May 2002 amendment to the contract reflects the addition of a **conversion rebate of up to 3%** for all prescriptions converted from Remeron Tablet to Remeron SolTab. A January 2003 amendment to the March 2002 agreement **extended the original ramp-up discount period through December 31, 2003**. Further, Organon pricing data for PharMerica demonstrates that PharMerica received these rebates until 2005.

G. Bonuses Paid to Pharmacy Managers Based on Medicaid Profit

116. McKenna disclosed to Relator Banigan in a conversation that took place after November 25, 2003 that he had handled the PharMerica account. During the Remeron Medicaid scheme, according to McKenna, compensation to PharMerica general managers and clinical directors was based in part on Remeron profit. Specifically, bonuses for both general managers and regional clinical directors were based upon weighted attainment of product initiatives. There were 22 products that qualified for this bonus, each of which was weighted and rated according to priority. Remeron Tablet had a priority rating of 8, which was based upon relative margin and opportunity to profit. PharMerica's initiative for Remeron Tablet was to shift the business away from other non-priority anti-depressants. When Remeron SolTab entered the market, discounts and rebates on Remeron Tablet were dropped to drive conversion to the new drug. Once this occurred, PharMerica eliminated Remeron Tablet' relative rating altogether and replaced the product on its list of initiatives with Remeron SolTab, which took the third slot in priority. Some of these discounts were passed onto the long-term care institutions, while a portion was retained by PharMerica and paid out as incentives to their site managers and clinical pharmacologists.

H. PharMerica's "Vendor of the Year" Status Tied to Financial Incentives

117. PharMerica also used its internal ranking system to reward pharmaceutical manufacturers, including Organon. PharMerica ranked pharmaceutical manufacturers according

to the amount of "rebate discounts" on their drugs and the amount of "contributions' (essentially cash gifts) these companies made to the vendor in partnership ("VIP") program at PharMerica. The VIP program had different levels of achievement, with Diamond Level being the highest a company could reach. In order to reach Diamond Level, a pharmaceutical company would have to contribute at least $150,000 per product to the VIP program. With recognition in the VIP program, a pharmaceutical company would receive additional support from PharMerica in implementing therapeutic interchange programs and other sales initiatives.

118. PharMerica would also choose a Vendor of the Year from the various high-ranking pharmaceutical manufacturers participating in the VIP program. Although Organon had only two products in the long-term car market, Remeron Tablet and Remeron SolTab, while other pharmaceutical companies, such as Pfizer or Bristol-Myers Squibb, had several products, Organon was ranked Vendor of the Year in 2002 at PharMerica. Organon also achieved Diamond Level in 2002, meaning that it provided in excess of $150,000 for both Remeron Tablet and Remeron SolTab.

I. Organon Decreased its Obligations Under its Rebate Agreements with State Medicaid Programs, and in One Instance Failed to Report the True Best Price

119. Organon was required to calculate its Average Manufacturer's Price ("AMP") by averaging the prices paid to the Organon for Remeron Tablet and Remeron SolTab by wholesalers for these drugs. In calculating its AMPs for Remeron Tablet and Remeron SolTab, Organon factored in the deep discounts that it illegally offered to pharmacy providers on these drugs, resulting in a lower AMP. Under the formula used to calculate Organon's rebate liability, a reduced AMP results in a lower rebate amount due Medicaid. Organon therefore decreased its liability under its rebate agreement with Medicaid by including illegally-discounted long-term

care prices in its calculation of AMP. Organon continued to reduce its rebate liability in this manner by extending these discounts for years.

120. Furthermore, Organon failed to report its best prices for Remeron Tablet and Remeron SolTab, thereby lowering its rebate liability. For example, in at least two instances involving the sale of short-dated Remeron SolTab product, Organon avoided disclosing the true best price.

121. In November 2001, Relator Banigan became personally aware of Organon's offer to Omnicare of a substantial quantity of Remeron SolTab at nominal prices in an effort to dispose of short-dated product. Organon selected Omnicare because Omnicare had not yet converted to Remeron SolTab. Both parties verbally understood that this offer was contingent upon Omnicare's later purchase of a similar quantity of Remeron SolTab at contracted discounts of 17%. By hinging the nominal price offer to a commercial sale, Organon willfully violated best price requirements by disclosing the transactions independent of one another. Had the two transactions been considered together, the best price calculation would have dramatically dropped by an estimated 40%.

122. Organon made a similar deal with PharMerica in the third quarter of 2001. Organon offered PharMerica a large amount of Remeron SolTab at a nominal price in order to dispose of Remeron SolTab that would expire quickly. This sale was conditional; PharMerica had to purchase a similar quantity of the drug at commercial prices. Organon structured the sale in a manner intended to defraud the government. In order to avoid disclosing the transaction, Organon sold the product to PharMerica through a wholesaler rather than by a direct sale to PharMerica. The result, however, is the same: Organon failed to report the true best price by

disclosing the transactions independent of one another even though best price requirements required Organon to report them together.

J. Introduction to Relators

i. Jim Banigan

123. Jim Banigan is a sixteen-year veteran of Organon, where he continues to work today. Banigan first came to Organon in 1991 as a sales representative. He was later promoted to become one of Organon's six original Regional Account Managers. He was then promoted to National Account Manager and began supervising Regional Account Managers. After five years with Remeron, Banigan became Manager of Government Accounts in 1996. In that position, he was responsible for Government Contracting and Government Contracts Administration, a position created for him and previously shared by several departments. Banigan became responsible for assuring that Organon drugs were on states' Medicaid formularies.

124. Banigan moved on to the Trade Department of Organon's National Accounts Division in early 2006, into an executive position in which he interacts with wholesalers, retail chains, and specialty pharmacies.

125. Although Banigan was not involved directly with the creation of the Medicaid scheme, he was a member of the leadership team within the same Managed Care department that developed the scheme and, as a result, had contemporaneous knowledge of it.

ii. Richard Templin

126. Richard Templin worked in management in the pharmaceutical arena for twelve years before joining Organon in March 2006. Templin, like Banigan, is an executive with Organon's Managed Markets Division and is the Director of Government Accounts. He was

hired by the Vice President of Managed Markets and currently reports to an Executive Leadership member.

127. When Templin first came to Organon, the Medicaid scheme was winding down; he eventually became aware of the scheme through the normal course of his job activities.

K. Relators' Discovery of Organon's Medicaid Scheme

128. Templin first became aware of the scheme to defraud Medicaid on Wednesday, September 27, 2006, while attending an Organon launch meeting at the Venetian Hotel in Las Vegas. Templin was having a conversation with John Maddox, an Executive Account Manager for Organon with responsibilities for both the Long Term Care and Managed Markets accounts. The topic of government compliance arose, and Maddox divulged the existence of a "non-compliant" program that provided him with a "get-out-of-jail-free card with Organon." Organon was undergoing significant management changes at that time and it was not uncommon for management and non-management staff to express concerns regarding their job security. Maddox did not offer any significant detail about the program. Templin did not pursue the topic further with Maddox that night, but decided to investigate further on his own.

129. Over the next few months, Templin was able to gather some information about the scheme Maddox had mentioned. He learned that the program centered on "marketing the spread" in the long-term care market and was focused exclusively on the product Remeron.

130. Templin broached the subject with a number of colleagues in late 2006 or early 2007, including Butch McKenna, Manager for Senior Care, National Accounts Division, who had created and managed the long-term care sales force. That sales force, Templin learned from McKenna, was set up specifically and with the expressed and written goal to implement the Medicaid scheme in the long-term care market. In addition, the long-term care sales force was

responsible for working collaboratively with the Government Accounts department, led by Jim Banigan, to secure formulary access for Medicaid patients, many of whom were residing in their customers' nursing home facilities.

131. McKenna disclosed to Templin that the program to which Maddox had alluded, marketing the Remeron spread to pharmacy providers, was called "Time to Profit." In fact, McKenna possessed copies of a long-term care marketing binder that detailed the scheme. McKenna mentioned that Organon's compliance officer Rhetta Rierdan had contacted him earlier with a request to return to the home office all marketing materials that dealt with marketing the spread, and McKenna, wishing to keep the binder, had falsely responded that he no longer had it. McKenna believed that the officer sought to destroy any materials he gathered. McKenna echoed Maddox's belief that the program was illegal and that he considered his knowledge of the program to be his "golden ticket" to raise if anything were to go wrong for him at Organon. As a result, he planned to continue to hold onto all related materials at his home office.

132. Templin first spoke to Jim Banigan about the Medicaid scheme in early April of 2007, hoping that Banigan had heard of it. Banigan confirmed the existence of the scheme. Banigan related that, in November of 2003, just as the scheme was winding down, Banigan heard about it from both McKenna, Director of Long Term Care Sales, and Maddox, Executive National Account Manager Long Term Care. Both discussions were prompted by changes in management and general concern over the leadership stability at Organon. McKenna had informed Banigan that he had direct knowledge of the Medicaid scheme and comprehensive documentation of marketing materials and other communications used to communicate to customers how to maximize their profits by influencing providers to prescribe Remeron.

McKenna had explained that the Marketing Department conspired with McKenna's sales team to market Remeron almost purely based upon spread and profit potential. McKenna had told Banigan that he planned to hold his knowledge of the scheme "close to his vest" for the time being, but that if Organon attempted to "squeeze him out," he would use this evidence as his "insurance policy."

133. In a separate conversation with Maddox a day after Banigan heard about this scheme from McKenna, Maddox, too, implicated the Marketing Department for producing materials used to highlight how to maximize profit and spread. Maddox indicated that the Marketing Department had recently become aware that the risk associated with continuation of this marketing scheme was too high. Maddox, McKenna and the rest of the long-term care sales team erased any evidence within their computers of selling-on-the-spread presentations and profit calculators. While Organon does have a general file retention policy requiring accounts managers to routinely clean out their electronic files, Maddox did not indicate to Banigan whether these actions of file destruction were brought about under that policy or from recommendations by general counsel for Organon.

134. Banigan had never seen for himself the marketing materials described by McKenna and Maddox, but after speaking with Templin, he decided to look for copies of those materials. He eventually secured original copies of two binders from former Remeron Executive brand director, Steve Vorrius, who had kept the original materials in his home. One of the binders was entitled "Long Term Care Sale Training" and the other was entitled "Remeron SolTab Therapeutic Interchange Program." Both have been described at length in Section Vof this Complaint. Banigan was not able to locate these binders internally at Organon. While Remeron-related marketing materials at Organon's offices are currently kept in a segregated

document review area at Organon's offices for litigation purposes, Banigan gathered from Steve Vorrius, Executive Brand Director, that these materials may have never been divulged in the course of litigation. After reading through the binders and learning how blatantly Organon had promoted the spread–along with added incentives–in the long-term care segment of Remeron's business, Banigan and Templin located and reviewed the contracts for Remeron's significant long-term care customers and found that the contracts' terms evidenced the same types of incentives reflected in the promotional materials. Moreover, the addenda to the contracts and accompanying communications reflected that as pressures mounted within Organon to grow the Remeron Tablet/Remeron SolTab business and to thwart impending generic competition, off-invoice discounts migrated to rebates. That move toward rebates assisted long-term customers in masking their true acquisition costs. In particular, rebates were preferred among long-term care providers who operated businesses within states in which Medicaid agencies benchmarked reimbursement upon actual acquisition cost.

135. Further, Banigan and Templin realized long-term care contracts had continuously been extended to guarantee maximum discounts. Those extensions would have required the cooperation of the sales, marketing, and account management groups. In addition, shared services such as legal, finance, and meeting planning would have had to be involved in order to secure approval and financial resources to support the scheme.

136. Banigan and Templin also located draft copies of both McKenna's and Maddox's 2001 business plans, which further evidence the promotion of "spread" and other financial incentives to pharmacy providers.

137. It was clear to Banigan and Templin by July of 2007 that Organon's upper management knew about the Medicaid scheme but wished to conceal its existence from

Medicaid and others. Further, Organon had not disclosed the scheme's existence to Organon's putative purchaser, Schering, during the parties' then ongoing due diligence period. In fact, executives were hiding evidence of the scheme in their homes in order to shield it from destruction by the Compliance Department.

IV. ACTIONABLE CONDUCT BY ORGANON, PHARMERICA, AND OMNICARE UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. The False Claims Act

138. This is an action to recover damages and civil penalties on behalf of the United States and Relators Banigan and Templin arising from the false or fraudulent statements, claims, and acts by Organon, PharMerica, and Omnicare made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

139. The False Claims Act ("FCA") provides that any person who knowingly submits or causes to be submitted to the United States for payment or approval a false or fraudulent claim is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

140. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

141. Based on these provisions, Relators Banigan and Templin, on behalf of the United States Government and the states of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico,

New York, Oklahoma, Tennessee, Texas, and Virginia and the District of Columbia (collectively the "states") seek through this action to recover damages and civil penalties arising from Organon's causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal Government for payment for Remeron Tablet and Remeron SolTab. Relators believe that the United States and the states have suffered significant damages as a result of false claims for payment for Remeron Tablet and Remeron SolTab. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relators are original sources as defined therein.

142. As required under the FCA, Relators have served an original disclosure statement of all material evidence and information related to this complaint on the Attorney General of the United States, the United States Attorney for the Southern District of Texas, and the Attorneys General of the various states and the District of Columbia.

ii. The Federal Anti-Kickback Statute

143. In pertinent part, the Anti-Kickback Statute provides:

(b) Illegal remuneration

1. whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

   (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

   (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

2. whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

   (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

   (A) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

3. Paragraphs (1) and (2) shall not apply to—
   (A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs, and civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

144. The purpose of the Anti-Kickback Statute is to prohibit such activities in order to secure proper medical treatment and referrals and to limit unnecessary treatments, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

145. Title 42, Section 1001.952(h) of the Code of Federal Regulations elaborates as to when a discount does not constitute a kickback. When a buyer submits a Medicaid claim, a seller does not violate the Anti-Kickback Statute for offering a discount or rebate on a drug if the seller: (1) fully and accurately reports the discount on the invoice, coupon, or statement submitted to the buyer; (2) informs the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report the discount; and (3) refrains from doing anything that would impede the purchaser from reporting the discount. *See* 42 U.S.C. § 1001.952(h)(2)(iii)(B).

146. Further, any payment to a group purchasing organization ("GPO") does not constitute "remuneration" under the Anti-Kickback Statute if: (1) the GPO has a written agreement with each member of the GPO that states that the participating sellers from which the members will purchase drugs will pay a fee to the GPO of 3% or less of the purchase price of the drugs provided by that seller or, if the percentage is greater than 3%, states the amount the GPO will be paid by each seller; and (2) when the members are health care providers, the GPO discloses in writing to the members at least annually the amount received from each vendor with respect to purchases made by or on behalf of the members. *See* 42 U.S.C. § 1001.952(j).

B. Fraudulent Conduct by Organon, PharMerica, and Omnicare Violates the FCA

i. Organon caused Long-Term Care Pharmacy Providers to Submit False Claims

147. In submitting reimbursement claims for Remeron Tablet and Remeron SolTab prescriptions, long-term care pharmacy providers targeted by Organon impliedly certified compliance with all laws applicable to federal and state funded healthcare programs. Organon knowingly or with reckless disregard for the truth caused and/or conspired with these long-term

care pharmacy providers to falsely certify compliance with the Anti-Kickback Statute when in fact Organon and these providers were violating this statute.

148. The government in turn reimbursed these providers based on these falsely-obtained prescriptions for Remeron Tablet and Remeron SolTab.

149. Further, Organon itself impliedly certified as a condition to participation in state Medicaid formularies that it was following all laws applicable to these programs, when in fact Organon and/or the long-term care pharmacy providers were systematically violating the Anti-Kickback Statute.

150. The Anti-Kickback Statute prohibits the offer or acceptance of remuneration to induce a physician to prescribe a drug. Organon violated the Anti-Kickback Statute by engaging in a fraudulent scheme to create and market the spread by offering significant discounts and rebates to its GPO and long-term care pharmacy provider customers in exchange for prescriptions for Remeron Tablet and Remeron SolTab. This scheme caused state Medicaid programs to pay excessive reimbursements for Remeron Tablet and Remeron SolTab to long-term care pharmacy providers.

151. Organon created the spread on the drugs by inflating AWP, then increased this spread by offering a number of financial incentives, including:

- Ramp-up discounts and rebates ranging from 8% to 14.8%, which were routinely extended beyond the initial offering period
- Conversion rebates of 3% or more for converting Remeron Tablet prescriptions to Remeron SolTab
- 1.5% therapeutic interchange bonuses
- Prompt pay discounts of 2%

In addition, Organon moved from offering discounts to offering off-invoice rebates, allowing long-term care pharmacy providers to hide their true costs.

152. Discounts and rebates qualify for the exemption under the Anti-Kickback Statute if three criteria are met: (1) Organon's invoice to the long-term care providers must fully and accurately report the discounts and rebates; (2) Organon must inform these customers of their obligations to report the discounts and rebates upon request to the Secretary of HHS; and (3) Organon must refrain from impeding these customers reporting the discounts and rebates. These financial incentives are not exempt from the safe harbor provision of the Anti-Kickback statute permitting discounts because Organon failed to inform long-term care pharmacy providers of their reporting obligations concerning the discounts and rebates and engaged in acts with these customers designed to keep them from reporting these discounts and rebates.

153. Organon reported the discounts it offered on Remeron Tablet and Remeron SolTab on its invoices to long-term care pharmacy providers until March 2001, when Organon transitioned to rebates in an effort to aid long-term care pharmacy providers in hiding their true costs of Remeron Tablet and Remeron SolTab.

154. Even for the period in which Organon listed the discounts on its invoices to these customers, Organon failed to meet the second criterion for the exemption to apply. Organon neglected to inform long-term care pharmacy providers of their obligations to report these discounts and rebates upon request to the Secretary of HHS. Although Organon had previously inserted such a provision into a 1998 contract with Owen, a GPO, it conspicuously omitted this provision in later contracts with GPOs and long-term care pharmacy providers.

155. Organon knew that its false price reporting and marketing efforts would cause its customers to submit claims for fraudulently-inflated Medicaid reimbursement.

156. Organon's fraudulent scheme to induce customers to purchase its products by ensuring that federal reimbursement rates for those products would be set at artificially inflated levels violated the Anti-Kickback Statute and the FCA.

a. Marketing the Spread Alone is a Kickback According to the Office of Inspector General for the Department of Health and Human Services

157. Given the complex calculation issues involved in Medicaid reimbursement and the fact that manufacturers serve a crucial role in the process, the Office of Inspector General for HHS ("OIG") has acknowledged the potential for fraud and openly addressed manufacturers regarding kickbacks. Acknowledging that AWP is used to set Medicaid reimbursement, the OIG noted on May 5, 2003 that it is illegal for a manufacturer to inflate the AWP and then actively market this spread for the purpose of inducing the purchase of a drug.

> The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. § 1395u (o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer

> from a subsequent purchaser (the federal of state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.
>
> In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736–23737 (May 5, 2003).

b. A Federal District Court Held that Marketing of the Spread Along with Financial Incentives Violates the Anti-Kickback Statute

158. In a case similar to this one, U.S. District Court Judge Patti Saris held in May of 2007 that marketing of the spread together with the direct offer of financial inducements is sufficient to allege a violation of the Anti-Kickback Statute. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, the United States intervened in a *qui tam* action against defendant Abbott Laboratories, Inc. ("Abbott"), to recover damages to Medicare and Medicaid programs. 491 F. Supp. 2d 12, 13 (D. Mass. 2007). The government claimed that Abbott reported inflated AWPs to drug pricing compendia and then marketed the spread, causing Medicare and Medicaid to overpay providers for Abbott's drugs. *Id.* The government contended that Abbott's actions violated the Anti-Kickback Statute by offering remuneration to its customers through marketing the inflated spread. *Id.* at 18.

159. In addressing Abbott's motion to dismiss, Judge Saris made clear that a direct offer of kickbacks to providers together with marketing the spread constituted a violation of the Anti-Kickback Statute. *Id.* at 19. In addition, Judge Saris indicated in *dicta* that, when a manufacturer intentionally publishes a falsely inflated AWP to induce the purchase of its product and markets the spread, the manufacturer has violated the Anti-Kickback Statute by making an indirect offer of remuneration. *Id.* (citing the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed.Reg. 23731, 23736 (May 5, 2003)).

ii. Organon Intentionally Decreased Its Rebate Liability to State Medicaid Programs

160. In submitting AMP and best price figures to CMS for Remeron Tablet and Remeron SolTab prescriptions, Organon knowingly or with reckless disregard for the truth made or used a false record or statement to conceal, avoid, or decrease its rebate payments to the state Medicaid programs owed under its rebate agreements.

161. Specifically, under the terms of the rebate agreements between Organon and the state Medicaid programs, Organon was required to pay rebates, the amount of which was premised on calculations involving AMPs and best prices for Remeron Tablet and Remeron SolTab, which Organon reported quarterly to CMS.

162. Organon intentionally used massive and illegal discounts and rebates offered to GPOs and long-term care pharmacy providers to lower its AMP figures for Remeron Tablet and Remeron SolTab, resulting in a reduction of its rebate liability for Remeron Tablet and Remeron SolTab to the state Medicaid programs.

163. Moreover, Organon avoided disclosing the true best price for Remeron Tablet and Remeron SolTab. For example, at different times, Organon offered to Omnicare and PharMerica

substantial quantities of Remeron SolTab at nominal prices contingent upon Omnicare and PharMerica's purchase of similar quantities of Remeron SolTab at a contracted discounted rate. Organon intentionally excluded the nominal price transactions when it reported its best price, even though it was required under best price law to disclose these transactions because they hinged upon a further purchase by Omnicare and PharMerica. Organon therefore failed to report its true best price.

164. Organon's intentional reduction of its reported AMPs for Remeron Tablet and Remeron SolTab and purposeful avoidance of reporting best prices violated the FCA and caused the federal and state governments to suffer substantial damages as a result.

iii. Organon Conspired with Its Long Term Care Customers to Defraud Medicaid in Violation of the FCA

165. Organon and long-term care pharmacy providers, including PharMerica, and Omnicare as well as NCS Healthcare, NeighborCare, and American Pharmaceutical Services (all presently owned by Omnicare) entered into agreements and conspired with one another to submit false claims for reimbursement for Remeron Tablet and Remeron SolTab prescriptions to state Medicaid programs and to receive reimbursement for these drugs to which the customers were not entitled.

166. As part of the scheme and agreement to obtain reimbursement for Remeron Tablet and Remeron SolTab prescriptions in violation of the state Medicaid programs' reimbursement policies, Organon and its long-term care customers conspired and agreed to perform acts to effectuate the conspiracy. Organon created the "spread" by reporting false, fraudulent and inflated drug prices for Remeron Tablet and Remeron SolTab to several price reporting compendia and offering further deep discounts and rebates to these customers. Organon then

marketed the spread to long-term care pharmacy providers and GPOs. Organon's business plan and sales materials demonstrate its aggressive marketing scheme based on the spread.

167. In furtherance of the conspiracy, Organon, PharMerica, and Omnicare entered into long-term contracts providing for financial incentives in the form of ramp-up discounts and rebates that were routinely extended beyond the initial offering period, conversion rebates, and therapeutic interchange bonuses. In addition, after complaints by long-term care pharmacy providers that these providers were passing through the discounts to the state Medicaid programs, Organon moved from offering discounts to rebates to allow long-term care pharmacy providers to hide their true costs.

168. Organon's contracts with these providers and GPOs assured an increased amount of prescriptions for Remeron Tablet and Remeron SolTab and thereby a larger profit for all parties involved. While earlier contracts between Organon and pharmacy providers for drugs other than Remeron contained a provision reminding both parties of their reporting obligations and that a discount is considered "illegal remuneration" under the Anti-Kickback Statute unless reported, this provision is conveniently absent in later contracts for the purchase of Remeron Tablet and Remeron SolTab.

169. In furtherance of the conspiracy, during the Remeron Medicaid scheme, compensation to PharMerica general managers and clinical directors was based in part upon the relative margin and opportunity to profit from Remeron Tablet and Remeron SolTab. In addition, PharMerica rewarded Organon Vendor of the Year in 2002 and Diamond Level for several years, for Organon's financial contributions to PharMerica's VIP program.

170. Organon, PharMerica, and Omnicare knew that their actions would result in the submission to state Medicaid programs of false and fraudulent claims for reimbursement for Remeron Tablet and Remeron SolTab, resulting in substantial damages to the United States.

iv. Damages

171. Remeron Tablet and Remeron SolTab scripts that resulted from false certification or conspiracy would not have been reimbursed by the state Medicaid programs, had the U.S. government or the states known the circumstances under which the requests for reimbursement were submitted and the laws violated by Organon, Omnicare, and PharMerica in order to claim reimbursement. Furthermore, Organon's false reporting of its AMP and best price for Remeron Tablet and Remeron SolTab resulted in a reduced rebate paid to the state Medicaid programs. Consequently, the states and the United States Government have suffered approximately $349.7 million in damages, which trebled is approximately $1.049 billion, stemming from improper Remeron Tablet and Remeron SolTab prescription costs.

VI. CAUSES OF ACTION

A. Count I - False Claims Act (31 U.S.C. § 3729)

172. Relators reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 169 this Complaint.

173. Based on the acts described above, Defendants knowingly violated one or more of the following:

i. knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

ii. knowingly makes, uses, or causes to be or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;